UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO THE TPP TRIAL SUBCLASSES	

TPP TRIAL DEFENDANTS' OMNIBUS MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTIONS IN LIMINE

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TPP TRIAL DEFENDANTS' RESPONSE TO MOTIONS

Plaintiffs' motions in limine—like their motion for partial summary judgment—essentially take the position that the Court should decide this matter instead of jurors by excluding all evidence on liability and damages that is contrary to Plaintiffs' theory of the case. Among other things, Plaintiffs contend that Defendants should not be allowed to present evidence that Defendants' VCDs served their intended function of effectively lowering consumers' blood pressure and provided economic value to consumers and TPPs. They also seek to block Defendants from presenting the jury with the FDA's repeated statements about the extremely low safety risk posed by the presence of trace amounts of nitrosamines in the VCDs. And Plaintiffs take the position that virtually any issue bearing on the sole class representative's credibility is off limits, while simultaneously seeking to portray Defendants as bad actors that allegedly put "profit" over "safety." (ECF 2569-1, 1.) This is not a proper use of motions in limine. "Motions in limine are a means of addressing the admissibility of evidence," not "for arguing that the opposing party's legal arguments on the merits of the case are incorrect." *Laskowski v. Dep't of Veteran Affs.*, No. 10cv600, 2011 WL 5040953, at *4 (M.D. Pa. Oct. 24, 2011); *see also, e.g.*, *Bowers v. Nat'l Collegiate Athletic Ass'n*, 563 F. Supp. 2d 508, 531-32 (D.N.J. 2008) (similar); *Clark Distrib. Sys., Inc. v. ALG Direct, Inc.*, No. 10-CV-2575, 2014 WL 12617412, at *1 (M.D. Pa. Sept. 11, 2014) (collecting cases)

(similar). Plaintiffs' motions should be denied for this and other reasons elaborated in greater detail below.

1. Defendants cannot assert that it is not appropriate to perform a retrospective analysis of their conduct or the consequences, including for example the resulting adulteration of the contaminated API and VCDs.

Plaintiffs argue that the Court should exclude evidence that it is inappropriate to perform a retrospective analysis of their conduct based on the Court's Rule 702 Order barring Teva's expert Roger Williams from opining that "VCDs could not have been 'adulterated' before the FDA became aware" of the existence of NDMA or NDEA. (ECF 2581, 17.) But the Court was clear that those opinions were merely excluded as improper "legal opinion[s]." (*Id.* at 16-17.) The Court likewise barred ***Plaintiffs'*** experts from offering their own legal opinions on adulteration and how it is judged. (*See id*. at 19.) Thus, if Plaintiffs attempt to offer a "retrospective analysis" by stating or implying, for example, that Defendants' products were "adulterated" because they did not comply with interim or final acceptable daily intake standards and/or test methodologies that ***did not exist*** at the time the products were being sold, Defendants should be free to challenge such a retrospective analysis and offer evidence to the contrary. *See, e.g., Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (retroactivity is "not favored" and "administrative rules will not be construed to have retroactive effect unless their language requires this result").

2. Defendants cannot defend their conduct by pointing to lack of knowledge or action by the FDA prior to ZHP's disclosure of the contamination in

June 2018, or blame or point the finger at the FDA in any way as a defense or excuse for their conduct.

Defendants do not intend to suggest—much less argue—that the FDA is at "fault" for the presence of NDMA and NDEA in their VCDs. However, Defendants must be allowed to show that even the agency tasked with overseeing the safety and efficacy of pharmaceuticals did not know of the potential for nitrosamine formation in these medications because that evidence is highly probative of whether Defendants knew or should have known of that possibility as well.

Plaintiffs' theory of the case is that Defendants should have recognized that the Zinc Chloride and TEA with quenching processes would produce nitrosamines, and their expert, Dr. Ron Najafi, goes so far as to claim that any process chemist in the pharmaceutical industry should have immediately recognized the risk of nitrosamine formation based on the presence of sodium nitrite and amines in the Zinc Chloride and TEA with quenching process. (*See, e.g.*, ECF 2292-6, 27-28; ECF 2292-4, 186:20-187:4.) However, as Dr. Najafi conceded, FDA chemists reviewed and approved the drug master files ("DMFs") that set forth the processes used by ZHP to manufacture valsartan API and did not recognize the fact that nitrosamines could form during the processes. (*See, e.g.*, ECF 2292-4, 189:1-19.) The fact that the federal agency charged with ensuring the safety of prescription drugs did not identify a risk of nitrosamine formation in ZHP's valsartan manufacturing processes is highly relevant to the question of whether every reasonable chemist knew or should have

known about the alleged risk. *See, e.g.*, *In re Bard IVC Filters Prods. Liab. Litig.*, 289 F. Supp. 3d 1045, 1049 (D. Ariz. 2018) ("*Bard*") (denying plaintiffs' motion in limine to exclude evidence that device manufacturer's product was approved for sale by the FDA under an expedited process); *Keen v. C.R. Bard, Inc.*, 480 F. Supp. 3d 646, 651 (E.D. Pa. 2020) (citing *Bard* and ruling the same).

Plaintiffs do not cite a single case holding otherwise. Instead, they argue that evidence of what the FDA knew and when is somehow irrelevant by speculating (based on ***their*** distorted interpretation of an FDA press release) that routine inspections of manufacturing facilities would not have uncovered the issues with nitrosamines (*see* Mot. at 4); accusing ZHP of lying in the DMFs by stating there were no genotoxic impurities in the API (*id.* at 5); and misrepresenting the FDA's Warning Letter as ascribing "blame" to ZHP (*id.* at 2-3). Defendants strongly disagree with these claims for all of the reasons set forth in their prior summary judgment briefing. But the pertinent point for purposes of this evidentiary dispute is that "[m]otions in limine are a means of addressing the admissibility of evidence, and it is an improper technique for arguing that the opposing party's legal arguments on the merits of the case are incorrect." *Laskowski*, 2011 WL 5040953, at *4; *see also, e.g.*, *Bowers*, 563 F. Supp. 2d at 531-32 (denying motion in limine for improperly "call[ing] upon the [c]ourt to weigh the sufficiency of the evidence in support of the parties' claims and defenses and in effect, to resolve the parties'

factual disputes"); *Clark Distrib. Sys., Inc.*, 2014 WL 12617412, at *1 (collecting cases) ("[M]otions in limine are intended to address the admissibility of evidence at trial, not dispositive issues more appropriately raised in a motion for summary judgment."). For all of these reasons, the motion should be denied.

3. Defendants cannot blame third-parties, including prescribing physicians, the FDA, or others, for the damages at issue.

Defendants have stipulated that they "will not blame physicians or assert that physicians were at fault for prescribing valsartan." (ECF 2639, ¶ 15.) But even assuming Plaintiffs were correct that the role of prescribers was supposedly "always known and foreseen" (Mot. at 6), Plaintiffs, as TPPs, would still have to establish: (1) that physicians prescribed the at-issue VCDs because of Defendants' alleged representations; (2) what drugs physicians would have prescribed in lieu thereof; and (3) whether those drugs would have cost the TPPs less money. *See, e.g.*, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014); *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2010 U.S. Dist. LEXIS 142767, at *23-24 (E.D. La. Mar. 31, 2010); *UFCW Loc. 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134-35 (2d Cir. 2010). Defendants are allowed to argue that Plaintiffs did not carry their burden of proving causation because they failed to introduce any evidence of these requirements.

4. Defendants cannot assert that the FDA statement advising patients not to discontinue their use of the VCDs until they could obtain a prescription for a replacement medication or treatment meant that the FDA did not

believe that there was an unacceptable health risk due to the contamination of the VCDs.

Plaintiffs' motion is meritless because the FDA's statement refutes Plaintiffs' theory that the at-issue VCDs were "worthless," which is the very heart of Plaintiffs' case. The FDA explicitly recognized that the risk to patients of ***not*** taking VCDs was far ***greater*** than the minimal risk of cancer. (Mot. Ex. 18, at 1.) Thus, the FDA's statement tends to prove that VCDs containing NDMA or NDEA had value because they effectively controlled patients' hypertension. As this Court has acknowledged, that is directly relevant to a "fundamental" trial issue, because "providing therapeutic value . . . ***belies economic worthlessness***" and is an issue to be resolved by the factfinder. (ECF 2261, 89 (emphasis added).) In addition, if Plaintiffs' punitive damages claim survives summary judgment—which it should not—evidence that the FDA instructed patients to continue taking their medications, despite the known presence of nitrosamines, weighs against a finding that Defendants' actions were so outrageous or egregious as to merit punitive damages. Accordingly, the FDA's statement is highly relevant and admissible under Rules 401, 402, and 403.

5. The FDA information statements regarding the valsartan and other sartans' contamination should not be referenced, or used to defend or deflect liability.

Plaintiffs essentially urge the Court to exclude ***any*** statement by the FDA regarding valsartan that is favorable to Defendants as being irrelevant and too confusing for the jury. (Mot. at 7-8.) In particular, Plaintiffs highlight a January 2019

pronouncement from the FDA stating, *inter alia*, "[b]efore we undertook this analysis, neither regulators nor industry fully understood how NDMA or NDEA could form during this particular manufacturing process." (*Id.* at 7-8 (quoting Mot. Ex. 19).) Statements like these are highly relevant because they speak to what industry knew and when regarding the potential for nitrosamine formation in the VCDs and are probative of Defendants' compliance with regulatory requirements. *See Keen*, 480 F. Supp. 3d at 650 ("[E]vidence of Bard's compliance with FDA regulations and the FDA's clearance of the G2 line of filters, while not dispositive, is relevant to the claims . . . ."). As the FDA has explained, "it needs to be recognized that the risk of an impurity can occur in order to know that it should be tested for." (ECF 2572 at Ex. 64, 5.) The applicable regulatory guidance standards similarly "limit[]" testing to issues "that might reasonably be expected based on knowledge of the chemical reactions and conditions involved." FDA Q3A § 3.1, https://www.fda.gov/media/71727/download (last accessed Feb. 24, 2024). While Plaintiffs are free to present their interpretation of FDA statements to the jury, the Federal Rules of Evidence apply "equally to both parties"; hence, Plaintiffs cannot pick and choose ***which*** FDA statements the jury gets to hear when deciding this case. *See In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2436, 2016 U.S. Dist. LEXIS 72774, at *5 (E.D. Pa. June 3, 2016) (Federal Rules of Evidence must apply in an evenhanded manner).

Plaintiffs also argue that allowing presentation of all relevant FDA statements would "confuse and mislead the jury" (Mot. at 8-9), but that is disingenuous. If Plaintiffs intend to argue to jurors that "[t]he FDA explicitly found that ZHP's API was adulterated in its November 29, 2018 Warning Letter" (*e.g.*, ECF 2569-1, 9-10), those same jurors are more than capable of ascertaining the FDA's position from the entirety of its relevant statements. Indeed, permitting Plaintiffs to cherry-pick which FDA statements are admissible would leave jurors with a slanted and distorted view of the FDA's position, creating the very kind of prejudice, confusion and misleading of the issues that Rule 403 is designed to prevent. *See, e.g.*, *Kader v. Sarepta Therapeutics, Inc.*, No. 14-cv-14318, 2016 WL 1337256, at *11 (D. Mass. Apr. 5, 2016) ("Because the FDA's October 30, 2014 statement is central to [p]laintiffs' allegations, the [c]ourt believes that other public comments from the FDA during the [c]lass [p]eriod should also be considered . . . ."); *Nolen v. C.R. Bard Inc.*, No. 19-cv-0799, 2021 WL 2115788, at *2 (M.D. Tenn. May 25, 2021) (denying motion in limine to exclude FDA evidence because "[i]t would make little sense to allow the defendants to only present the portions of that [FDA] history that reflect well on Bard").

6. Defendants cannot assert that there was an industry-wide problem, or that industry standards did not require them to identify and control all genotoxic impurities from their manufacturing processes.

Plaintiffs contend that because it is Defendants' "conduct that is at issue in

this trial," they should not be permitted to argue or present evidence that there was an industry-wide problem, or that industry standards did not require Defendants to identify and control all genotoxic impurities from their manufacturing processes. (Mot. at 9.) However, it is blackletter law that "evidence of industry standards . . . is relevant" to claims for breach of express warranty and fraud like those asserted in this case. *Axiall Corp. v. Descote S.A.S.*, No. 15-CV-00250, 2017 WL 9487085, at *5 (W.D. Pa. Oct. 27, 2017), *report & recommendation adopted by* 2017 WL 5957748 (W.D. Pa. Dec. 1, 2017).

Rather than address relevance and admissibility, Plaintiffs assert that the "FDA unequivocally rejected ZHP's effort to hide behind this being a problem across the industry, and purported but not defined industry practices or standards." (Mot. at 9.) Defendants, however, have presented evidence to refute this point, such as the FDA Commissioner's statement that "neither regulators nor industry fully understood how NDMA could form" during ZHP's manufacturing process. (*See* ECF 2571, ¶¶ 61-63 (quoting ECF 2572 at Ex. 1, 1; ECF 2572 at Ex. 64, 4).) While Plaintiffs are entitled to argue their interpretation of FDA statements and other evidence, Defendants have a fundamental right to present theirs, with "the jury" being the ultimate "finder of fact and weigher of credibility." *United States v. Gonzalez*, 155 F. App'x 580, 582 (3d Cir. 2004) (quoting *United States v. Abel*, 469 U.S. 45, 52 (1984)).

The undeniable fact is that the recent discovery of nitrosamines in the U.S. drug supply was a far-reaching industry-wide issue that affected, and continues to affect, numerous medications and manufacturers well beyond those in this case. This context is highly relevant to Plaintiffs' claims that the TPP Defendants engaged in unfair or deceptive trade practices and that their conduct was so outrageous and egregious as to warrant punitive damages.

7. ZHP Defendants cannot disclose or rely on hearsay discussions with Jinsheng Lin, Ph.D., or other sources, to assert translation or interpretation of the July 27, 2017 email that differs from 30(b)(6) testimony of Min Li, or ZHP's translation.

The ZHP defendants oppose this motion to the extent it would bar them from appropriately clarifying any deposition testimony provided by Jucai Ge regarding the July 27, 2017 Jinsheng Lin email. Ms. Ge is in the process of attempting to obtain a visa to travel from China to the United States to testify live at trial. If that effort is unsuccessful due to circumstances outside of Ms. Ge's or the ZHP defendants' control, the ZHP defendants anticipate that Plaintiffs will present Ms. Ge's deposition testimony as a corporate representative at trial, including testimony about the July 27, 2017 email. If such testimony were admitted, the rule of completeness requires that Ms. Ge's full testimony on this topic, including her interpretation of the email after speaking with Dr. Jinsheng Lin in her role as a corporate representative, also be admitted. *See* Fed. R. Evid. 106.

8. Defendants cannot assert or argue that NDMA and NDEA are not, and

were not known to be at all relevant times, genotoxic, probable human carcinogens.

Plaintiffs' MILs 8 and 9 are both premised on the same argument: because NDMA and NDEA have been classified by the International Agency for Research on Cancer ("IARC") and others as "probable human carcinogen[s]," Defendants should be precluded from presenting any evidence or argument that trace amounts of these impurities in the at-issue VCDs were not genotoxic or carcinogenic. To be clear, Defendants do not intend to deny that NDMA and NDEA have been classified by IARC as "probable human carcinogens." But Defendants should not be precluded from presenting epidemiological and other scientific evidence demonstrating the absence of a connection between the trace levels of nitrosamines found in the at-issue VCDs and cancer. In addition, Defendants should not be precluded from telling the jury that the FDA estimated that if 8,000 people took the highest valsartan dose of 320 mg containing NDMA daily for four years—***the absolute maximum possible intake by any user***—there may be one additional case of cancer over the lifetimes of the 8,000 people.[1] Similarly, Defendants should not be precluded from presenting evidence regarding: the allowable daily intake of these nitrosamines; permissible daily exposure limits; and the amount of NDMA that is efficiently eliminated by the liver and does not result in systemic exposure to other tissues and organs. Defendants

[1] (ECF 2572 at Ex. 64.)

should also be permitted to inform the jury that there are acceptable levels of NDMA in pharmaceuticals permitted by the FDA even today.[2] Telling the jury that NDMA and NDEA are "genotoxic, probable human carcinogens" without placing that in context by explaining that these nitrosamines appear in the at-issue VCDs only in trace amounts not shown to cause injury creates an unacceptable risk of juror confusion. Fed. R. Evid. 403.

9. General causation is not an element of the claims at issue, and is not an issue to be determined at trial.

When this Court announced that the first trial in this MDL would be a TPP economic loss trial, it specifically emphasized the need to try general causation:

> The personal injury cases are just too idiosyncratic for us to get the answer to the ***first and most important questions here, which is general causation***. So we'll pick a case if we have to, ***probably a third-party payor case*** because the damages are relatively easy to calculate in those cases, and ***just to get a jury to say yes or no on the question of general causation and get that done***.

(ECF 1946, 41:6-12 (Kugler, J.) (emphases added).) Plaintiffs' efforts to avoid the general causation issue would undermine the fairness of trial and fail to accomplish the Court's stated goals.

First, Plaintiffs argue that general causation is not an element of their claims, but that is beside the point. As this Court has acknowledged, "***causation carries***

[2] Defendants incorporate their response to Plaintiffs' MIL 9, which sets forth other examples of the anticipated testimony and evidence relevant to this question, by reference here.

over" into the economic loss class actions, because "if the contamination is ***not dangerous***, then maybe [Plaintiffs] ***don't have such a great argument that [they] should get [their] money back*** for paying for it." (ECF 77, 5:12-16 (Kugler, J.) (emphases added).) The Court likewise recognized in its class certification order the "very large disagreement between the parties as to the economic value" of the at-issue VCDs, and identified Plaintiffs' "worthlessness" theory as a "central trial issue." (ECF 2261, 37-38 & n.27.) *See also In re Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 2924, 2023 WL 4765409, at *8 (S.D. Fla. July 25, 2023) (holding that without proof of cancer causation from nitrosamine impurities, the plaintiffs "lack any basis—through pleadings or evidence—to advance the proposition that ranitidine is worthless, with a value of zero").

Plaintiffs' breach of express warranty, fraud, and consumer protection claims are all predicated on allegations that, *inter alia*, Defendants represented or warranted their VCDs were "safe," met "safety" requirements, and "have the same safety and efficacy profile" as their brand-name equivalents, when, according to Plaintiffs, the VCDs were actually "unsafe," "less safe," "carcinogenic," "genotoxic," or "do not possess" or "did not have" the "same safety and efficacy profile" as their branded equivalents. (*See, e.g.*, ECF 1708, ¶¶ 171, 204, 212-213, 222, 237-238, 250, 282, 381, 388, 413, 417, 423-425, 427, 432, 444, 450-451, 621, 631, 728-730, 735, 784, 793.) Whether Defendants breached an express warranty, made a material

misrepresentation, or engaged in deceptive or unfair practices with respect to their products' safety, i.e., whether their products can cause cancer, are "elements of the claims at issue" requiring the jury to consider general causation evidence.

Second, Plaintiffs' catalogue of the exhibits they intend to present regarding "contamination levels," "acceptable daily limit[s]," classification of NDMA and NDEA as "highly toxic substances" in the "cohort-of-concern," and "unacceptable carcinogenic risk" only serves to highlight why it would be highly prejudicial to exclude general causation evidence. Plaintiffs will seek to prove through their cited exhibits that Defendants sold dangerous and "worthless" drugs. Defendants, in turn are entitled to inform the jury, in part through the presentation of general causation evidence and the FDA's own contemporaneous statements, that although their products were found to contain an unexpected impurity, they were nevertheless safe and effective and had value to their purchasers. For example, Defendants' expert Lewis Chodosh, M.D., Ph.D. opines that the theoretical maximum levels of NDMA exposure from Defendants' VCDs are orders of magnitude lower than the lowest levels observed to cause cancer in experimental animals. (*See* Am. Rep. of Lewis Chodosh, M.D., Ph.D. ¶¶ 154-160, Sept. 24, 2021 (Ex. 1 to the Certification of Jessica Davidson ("Davidson Cert.")).) And an epidemiological study, the Pottegard study, reported no statistically significant elevated overall risk of cancer after exposure to NDMA-containing valsartan products. (*See* Pottegard et al., *Use of N-*

nitrosodimethylamine (NDMA) contaminated valsartan products and risk of cancer: Danish nationwide cohort study. BMJ. 2018;362:k3851 (Davidson Cert. Ex. 2).)

Plaintiffs cannot have it both ways. If they intend to present evidence, elicit testimony, or refer to Defendants' VCDs as toxic and carcinogenic, fairness and due process dictate that Defendants be permitted to offer countervailing evidence to assist the trier of fact in evaluating that risk.

Third, there is no merit to Plaintiffs' argument that introducing general causation evidence would "requir[e] the testimony of many witnesses, and a much longer trial," which, in Plaintiffs' view, would "thoroughly mislead and confuse the jury." General causation is not an "irrelevant mini-trial," but the "first and most important question" to be tried. Plaintiffs have made no showing that the probative value of this pivotal evidence is substantially outweighed by the danger of unfair prejudice, confusion of the issues, misleading the jury, or undue delay. Fed. R. Evid. 403. If anything, the danger of unfair prejudice, confusion and misleading the jury would all be heightened by ***excluding*** critical general causation evidence. And while such evidence would undoubtedly involve some additional testimony and exhibits, it is likely that one, or at most two, additional witnesses per side will suffice on this subject. Allowing general causation experts to testify on discrete matters relevant to these issues will not unduly prolong the trial or confuse the jury; it will ensure a fair trial.

10. Defendants cannot reference or assert the Valisure Citizen Petition, in any way, including but not limited to with regard to Dr. Najafi, nor can they use the Valisure Citizen Petition to assert that brand diovan contained NDMA or NDEA.

Valisure submitted a Citizen Petition to the FDA in June 2019 that included the results of testing certain lots of VCDs for the presence of NDMA. The Citizen Petition showed detectable levels of NDMA in the majority of samples identified as Novartis valsartan product. (*See* Valisure Citizen Petition at Appendix A (ECF 1984-1).) The only valsartan product sold by Novartis in the United States was Diovan, the Reference Listed Drug ("RLD") for the generic VCDs at issue in this case. Plaintiffs' arguments that this evidence constitutes inadmissible hearsay and is both irrelevant and prejudicial are meritless.

First, the Court has already held that the ZHP defendants' regulatory expert Dr. Ali Afnan may offer opinions and testimony regarding the Citizen Petition and its findings. (*See* ECF 2581, 6-7 (holding that the portion of Dr. Afnan's report regarding the Citizen Petition and its finding that branded Diovan (the RLD) was contaminated with nitrosamines (*see* Mot. Ex. 19, ¶ 212) is "NOT PRECLUDED").) An expert can rely on out-of-court statements, and the jury may consider those statements, if the "probative value in helping the jury evaluate [the expert's] opinion substantially outweighs [its] prejudicial effect." Fed. R. Evid. 703. It is hard to imagine any evidence more probative "in helping the jury evaluate" Dr. Afnan's opinion that Diovan contained NDMA than the document providing the basis for

that opinion. *See, e.g.*, *Princeton Digital Image Corp. v. Off. Depot Inc.*, No. 13-239 et al., 2017 WL 10765194, at *3 (D. Del. Aug. 1, 2017); *In re Terazosin Hydrochloride Antitrust Litig.*, No. 99-MDL-1317, 2005 WL 5955699, at *6 (S.D. Fla. Feb. 2, 2005) (jury could consider letter to FDA under Rule 703 since "the jury would be unable to evaluate the [e]xperts' opinions if the [c]ourt did not allow disclosure of" the letter).

Second, Plaintiffs' argument that the Citizen Petition is irrelevant to, and inadmissible to challenge the opinions of, their regulatory expert, Dr. Ron Najafi, is also baseless. The Court has repeatedly held that Valisure's identification of NDMA in Novartis product is relevant to both Plaintiffs' claims and Dr. Najafi's opinions. Specifically, in July 2022, the Court entered an order compelling Dr. Najafi to produce a variety of materials related to the Valisure testing. (*See* ECF 2137, 6.) As the Special Master explained, both Plaintiffs and Dr. Najafi have taken the position that, unlike the recalled VCDs, the RLD "contain[s] zero NDMA and zero NDEA." (*Id*. at 2 (citation omitted).) Thus, the "presence of nitrosamines in the RLDs would undermine" Plaintiffs' position that generic valsartan products are "not the same as the RLDs." (*Id*.) In addition, the Special Master noted that detection of NDMA in the RLD would "undermine" the validity of Dr. Najafi's opinions—and therefore materials related to Valisure's testing of Novartis product "are clearly relevant to" Plaintiffs' claims. (*Id.* at 2, 5.) This is particularly true because Dr. Najafi testified

that he was involved in validating some of the testing underlying the Citizen Petition.

In response to the ZHP defendants' subsequent motion to compel Valisure to provide the National Drug Code ("NDC") numbers for the Novartis samples in which it identified NDMA, the Special Master once again confirmed the relevance of Valisure's testing to Plaintiffs' claims but denied the discovery as untimely because it was issued after the close of the fact discovery period. (*See* ECF 2476, 3 (Special Master finding that Valisure's testing was relevant and that "discovery had been ordered with respect to the purported validation of the Valisure testing by one of Plaintiffs' experts, Dr. Najafi").) And in its own review of the Special Master's order, this Court agreed that Valisure's testing "***was relevant***" but found that the "ZHP defendants may have realized too late a particular significance of Valisure's information" and therefore the subpoena for more information was untimely. (ECF 2554, 2 (emphasis added).)[3]

Third, there is no merit to Plaintiffs' argument that the evidence would be unduly prejudicial. Plaintiffs assert that Valisure's testing is unreliable because the

[3] In addition, Dr. Najafi's reliance list includes the expert report of Dr. Afnan, which describes, and cites, the Valisure Citizen Petition. Defendants are therefore entitled to question Dr. Najafi on why he ignored that evidence in asserting that the RLD for valsartan does not contain NDMA. *See Tucker v. Evenflo Co.*, No. 20-cv-2, 2021 WL 8946698, at *6 (M.D. Fla. Nov. 29, 2021) ("The [c]ourt agrees that any document listed by Evenflo's expert as background material in the expert's report may be inquired into on cross-examination.").

FDA sent a letter to Valisure in December 2022 criticizing some of the lab's testing. (Mot. Ex. 53.) But the FDA letter related to an inspection of Valisure in Summer 2021, long after the Citizen Petition was submitted, and it referenced testing related to ***other*** products and potential impurities. (*See id.*) Plaintiffs also note that Health Canada did not identify NDMA in the valsartan RLD, but this does not render Valisure's testing inherently unreliable or unduly prejudicial, particularly since Dr. Najafi expressly validated some of Valisure's results, demonstrating the lab's reliability. (*See* ECF 2009-7 at Ex. 52, 144:8-145:15; ECF 2023-3.) It would be prejudicial to bar Defendants from raising this highly relevant evidence at trial.

11. Defendants cannot argue that the specifications for the valsartan API and VCD's permitted the NDMA and NDEA contamination/that the specifications did not prohibit the NDMA and NDEA contamination.

Plaintiffs unfairly seek to prevent Defendants from informing the jury what the FDA-approved DMF and ANDA specifications for the valsartan API and finished-dose VCDs actually said, including that Defendants' products complied with the specifications' impurity limits. Defendants intend to present evidence that they complied with all FDA-approved specifications in the production and marketing of their VCDs, and should not be precluded from accurately presenting these facts of their case. Aside from the prejudice Defendants would suffer if they are unable to tell the jury that they complied with all specifications, adherence to the FDA-approved specifications is relevant to the claims and defenses at issue because

it is directly probative of Plaintiffs' allegations that Defendants misrepresented and breached warranties of compliance with these same specifications. (*See, e.g.*, ECF 1708, ¶¶ 171, 244-245, 251, 256, 288, 417, 428.)

To this day, the FDA has not banned any pharmaceuticals on the sole basis that they contain some detectable amount of NDMA, and no valsartan USP monograph prohibits its presence. Rather, impurity limits exist, as they also did from 2013 to 2018—and NDMA is no exception to these limits. The jury must be able to hear that Defendants were within such compendial limits for impurities, all of which were built into the applicable specifications during the relevant time period.

12. Defendants cannot argue that their VCDs were not adulterated because they complied with the USP monograph for valsartan.

Plaintiffs unfairly seek to prohibit Defendants from arguing that their VCDs were not adulterated because they complied with the USP monograph for valsartan. Plaintiffs contend that such an argument would be "misleading" and "unfair" because ***they*** construe the USP monograph for valsartan as not permitting NDMA or NDEA in any amount. (Mot. at 23-24.)

Defendants strongly dispute Plaintiffs' points and cited record evidence refuting them in their summary judgment briefing. (*See, e.g.*, ECF 2602, ¶ 41; ECF 2571, ¶ 118; *see also* ECF 2571, ¶¶ 68, 72-73.) It is procedurally improper for Plaintiffs to simply repackage their summary judgment theory of adulteration under the guise of a motion in limine, as the authorities cited on pages 4-5, above, make

clear. Accordingly, and particularly in light of this Court's pronouncement that whether the VCDs were "adulterated" "is only for the fact-finder to reach" (ECF 2581, 19), this motion should be denied.

13. Defendants cannot argue "all drugs have impurities."

Plaintiffs argue that Defendants should not be allowed to discuss at trial that drugs have impurities because "the n-nitroso class of impurities is controlled very differently from non-genotoxic" ones. (Mot. at 24.) Even putting aside that the "very different[]" treatment of n-nitroso impurities is a recent development arising only after the discovery of NDMA in valsartan, the scientific fact that all drugs contain impurities is an important backdrop for—and highly relevant to—the claims and defenses in this case. Plaintiffs claim that the at-issue VCDs contained impurities that were not listed in valsartan's USP monograph, whereas Defendants argue that their VCDs complied with all compendial requirements that were in force at the time, including all impurity requirements. (ECF 2569-1, 7, 19-22; ECF 2571, ¶¶ 98-101.) Moreover, in response to Plaintiffs' allegations of cGMP violations, Defendants will prove to the jury that testing VCDs for nitrosamines was not required by the FDA. (ECF 2571, ¶¶ 21, 31.) Defendants also intend to present evidence that "changes in impurities do not create different or new drugs" because they do "not implicate pharmaceutical equivalence, bioequivalence, or AB ratings." (ECF 2571, ¶¶ 92-94.) Therefore, to decide these claims and defenses, the jury necessarily needs to

understand what kind of information USP monographs contain, what impurities are, and how the FDA regulates the presence of impurities in drugs sold in the United States. Moreover, much of the evidence and testimony will focus on the key ICH guidances governing the content and qualification of impurities in drug substances and products, which will lead to confusion if Defendants are not able to inform the jury that impurities can and do occur.

While Plaintiffs contend that this evidence is somehow "confus[ing] and mislead[ing]" under Rule 403 (Mot. at 24), they do not attempt to explain their argument. Pointing out the scientific reality that drugs contain impurities cannot be misleading because it is true. Nor can it be confusing because it will help the jury understand the parties' claims and defenses in their proper context.

14. Defendants cannot refer to the "alleged" presence of "purported impurities" or similar language, or dispute that all of the at-issue valsartan was contaminated, including untested lots (if any) at levels above the limits set by the FDA.

Defendants oppose this motion to the extent it seeks to preclude Defendants from arguing that the at-issue VCDs were not "contaminated" at a level capable of causing injury or rendering them economically worthless. (*See supra*, Opp'n to MILs 8 and 9.) In all other respects, Defendants do not oppose this motion.

15. Defendants filed no cross-claims for contribution/indemnification, and disclosed no experts to do so, and should be precluded from asserting evidence or making arguments consistent therewith, including that a co-defendant was at fault, or liable for Plaintiffs' damages.

Defendants do not intend to argue to the jury that any other co-Defendant at trial was "at fault" or "liable for" Plaintiffs' claimed damages. As Plaintiffs correctly point out, there are no asserted cross-claims in this trial between the current co-Defendants; accordingly, no Defendant will be asking the jury to determine the fault or liability of any other existing co-Defendant.

Defendants should not, however, be prevented from differentiating their conduct and regulatory determinations from those of co-Defendants, such as the fact that Teva and Torrent did not receive any warning letter from the FDA relating to their VCDs. Nor should Teva and Torrent be precluded from presenting factual evidence of and highlighting the reality of their distinct circumstances relative to ZHP. For example, Plaintiffs are expected to rely heavily on the July 27, 2017 email from ZHP witness Jinsheng Lin in their quest to show ZHP's supposed pre-existing knowledge of the potential for nitrosamine formation from the route of synthesis. There is no evidence that Teva or Torrent were privy to any information shared internally at ZHP, whatever its interpretation may be. Accordingly, co-Defendants should be entitled to present the facts in this manner, without limitation, as long as co-Defendants are not asking the jury to assign liability to, or award damages against, another party.

16. Defendants cannot assert the cost of replacement drugs or therapies.

Plaintiffs seek to preclude Defendants from introducing evidence that

Plaintiffs would have had to pay for replacement drugs if the at-issue VCDs had not been on the market and whether these replacement drugs would have cost TPPs less money. While Plaintiffs argue that the Court "already determined that Defendants' VCDs were economically worthless" (Mot. at 27-28 (citing ECF 775, 20)), the Court merely found that Plaintiffs had "alleged sufficient injury and the lack of the VCDs' functionality ***at the motion to dismiss stage***." (ECF 775, 20 (emphasis added).) The Court has not "determined" that Plaintiffs' theory of injury is valid, much less ruled that Defendants are precluded from challenging it. To the contrary, the Court has specifically acknowledged the "very large disagreement between the parties" regarding Plaintiffs' theory that the VCDs were "economically worthless," and identified it as a "***central trial issue***." (ECF 2261, 37-38 & n.27 (emphasis added).)

It is critical that Defendants be permitted to challenge Plaintiffs' ability to prove injury by introducing the cost of replacement drugs and their prices because, in calculating any damages, jurors must "consider the difference between what [the plaintiff] paid for the drug and the cost of an alternative medication." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 325 F.R.D. 529, 540 (D. Mass. 2017); *see also Sergeants Benevolent*, 20 F. Supp. 3d at 328 ("[T]o calculate the injury to [p]laintiffs, one would have to consider several variables, including the alternatives to Ketek that could be prescribed for a particular condition and the relative costs of those alternatives."). Defendants intend to present real-world evidence of

replacement drugs for that legitimate purpose, including testimony from their experts, Plaintiffs' own admission that they would have had to pay for other hypertension drugs, the actual prices for these replacement drugs, and Plaintiffs' actual costs following the recall. (*See* ECF 2009-3 at Ex. 29, 208:5-13; ECF 2009-19, 30-34; ECF 2630-1, ¶¶ 33, 38-40 ("Dr. Conti at best considers only one half of the equation—the amount spent by TPPs for the at-issue VCDs, while failing to consider the other half—what Plaintiffs would have paid in an alternative scenario.").) The Court should permit this evidence and deny Plaintiffs' motion.

17. Defendants cannot assert that the contaminated VCD's had value based on their efficacy.

In direct contradiction of this Court's prior rulings, Plaintiffs ask the Court to prevent Defendants from introducing evidence that the at-issue VCDs had value because they were therapeutically effective. The Court's class certification ruling expressly recognizes that the "fundamental issues" for trial include Plaintiffs' expert Dr. Conti's theory of worthlessness and Defendants' expert Dr. Stiroh's countervailing view "that VCDs, although contaminated, did lower consumers' high blood pressure, ***thereby providing therapeutic value, which belies economic worthlessness***." (ECF 2261, at 89 (emphasis added).) The Court concluded that this dispute was to be left "***for the factfinder***." (*Id.*) *See also Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 557-58 (E.D. Pa. 2019) (holding that whether Dr. Conti's "damages calculation is improper" due to her

failure to account for "any therapeutic value . . . received from the noncompliant drugs" is "necessarily a credibility dispute between the parties' experts").

18. Defendants cannot reference, assert, or rely on opinions of defense experts that rely on the precluded opinions of other defense experts. For example, Dr. Afnan's opinions that rely on Dr. Xue's precluded opinions.

Dr. Afnan will not reference, assert or rely on any of Dr. Xue's precluded opinions. As long as that is the extent of the motion, Defendants do not oppose it. As set forth in Defendants' pending opposition to Plaintiffs' cross-motion, however, the parties disagree on the extent to which Dr. Afnan relied on Dr. Xue. (*See* ECF 2651, 6-15.) The Court already reviewed and admitted the majority of Dr. Afnan's opinions based on his own qualifications and expertise as both a chemist and a former FDA regulator. (*Id*. at 7-8.) As a result, there is no basis to preclude any of those opinions under the guise of a motion in limine.

19. Defendants cannot argue that the relevant warranties only went to the prescribers.

Plaintiffs seek to preclude Defendants from "argu[ing] that since patients rely on their physicians who prescribe the medication, the only representations that are relevant are those directed to the prescribers." (Mot. at 30.) Plaintiffs misconstrue Defendants' argument. Defendants do not argue that ***only*** representations made to physicians matter at trial. Rather, both representations made to physicians and the absence of representations made to TPPs are essential to Plaintiffs' claims.

To prevail on their claims, Plaintiffs must establish that Defendants made

misrepresentations to the TPPs, and that the TPPs relied on them. (ECF 2558-1, 2; ECF 2562-1, 17-22; ECF 2569-1, 28.) But Plaintiffs must also establish that physicians prescribed the at-issue VCDs because of representations made by Defendants. Such evidence is necessary to prove that Defendants' actions were the proximate cause of Plaintiffs' alleged injury, as explained above. (*See supra*, Opp'n to MIL 3 (proximate causation requires that Defendants' challenged statements must have caused the prescription of their VCDs).) Evidence showing that Plaintiffs have not satisfied prima facie elements of their claims is not confusing or misleading. *See* Fed. R. Evid. 403. To the contrary, precluding such evidence would mislead the jury by denying them access to relevant evidence that goes to the heart of Plaintiffs' causes of action.

20. Defendants cannot argue they are good companies, the "societal benefits" of their VCDs and other products, or the cost of drug research and development.

Plaintiffs seek to preclude Defendants from arguing or suggesting that they are "good companies," manufacture drugs that benefit society, make charitable contributions, or otherwise engage in good acts. (*See* Mot. at 31-33.) Plaintiffs' motion should be denied for multiple reasons.

First, Plaintiffs' motion is overly broad and would improperly prevent Defendants from offering necessary context about their businesses, unfairly limiting their defense. *See Johnson v. C.R. Bard Inc.*, No. 19-cv-760, 2021 WL 2070448, at

*8 (W.D. Wis. May 24, 2021) (denying plaintiff's motion in limine as "overly broad" and permitting defendants to offer evidence "including the nature and usefulness of Bard's products, as well as the conscientiousness of its employees"). Indeed, "[t]he jury are entitled to know the identity and nature of the parties appearing before it." *Carrel v. Nat'l Cord & Braid Corp.*, 852 N.E.2d 100, 112-13 (Mass. 2006) (affirming trial court's denial of plaintiff's motion in limine to exclude evidence of the "nature" of the defendant corporation, including "how many people they have and the fact that it is a family institution") (citation omitted); *see also Acantha LLC v. DePuy Orthopaedics, Inc.*, No. 15-C-1257, 2018 WL 2431852, at *2 (E.D. Wis. May 30, 3018) (similar).

The sole example of a purportedly improper "good-company" argument provided by Plaintiffs is consistent with these principles. According to Plaintiffs, ZHP's trial counsel inappropriately argued to another jury in an ongoing product-liability trial that "[y]ou don't stay in business as long as J&J has by doing the types of things that were alleged here this morning." (Mot. at 31-32 (quoting Mot. Ex. 61, 543:20-24).) However, as the attached transcript makes plain, this one comment was part of an entirely permissible discussion of the defendant's founding, the number of its employees, and the ubiquity of its product across the globe (Mot. Ex. 61, 543:13-544:11)—all of which constitute legitimate "background" facts. *Acantha*, 2018 WL 2431852, at *2; *Carrel*, 852 N.E.2d at 112.

Contrary to Plaintiffs' claim, such limited argument would not "open the door to a barrage of negative evidence directed at Defendants." (Mot. at 32.) "The Rules of Evidence do not simply evaporate when one party opens the door on an issue." *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 784 (5th Cir. 2018) (citation omitted). Nor is evidence of good acts or philanthropy barred by Rule 404(b). As Plaintiffs' own cases recognize, Rule 404(b) prohibits evidence of good acts only if that evidence is used for the ***sole*** purpose of "establish[ing] the defendant's good character." *United States v. Hayes*, 219 F. App'x 114, 116 (3d Cir. 2007). Evidence of good acts ***is*** "admissible for a proper purpose such as motive, intent, absence of mistake, etc." *Id.*; *Ansell v. Green Acres Contracting Co.*, 347 F.3d 515, 519-23 (3d Cir. 2003) (affirming district court's decision to admit evidence of good acts under Rule 404(b)). Here, as explained above, evidence of Defendants' work in the community and other good acts is not being offered for the sole purpose of establishing Defendants' good character, but rather may be relevant to explain the nature of their business and the job responsibilities of witnesses.

Second, "good company" evidence is also relevant to Plaintiffs' claims for punitive damages. While Plaintiffs contend that Defendants put "profit" over "safety" (ECF 2569-1, 1), evidence regarding the "usefulness of their products" and "the fact that their products are designed to promote health and save lives" is capable

of "rebut[ting]" that theory. *See, e.g.*, *In re Bard IVC Filters Prods. Liab. Litig.*, No. 16-00474, 2018 WL 934795, at *2 (D. Ariz. Feb. 15, 2018) (permitting such evidence "to rebut [p]laintiffs' punitive damages claim" and corresponding allegation that "[d]efendants knowingly disregarded patient safety . . . and placed profits over safety"); *In re Wright Med. Tech. Inc.*, No. 13-cv-297, 2015 WL 6690046, at *3 (N.D. Ga. Oct. 30, 2015) (denying plaintiff's motion to exclude evidence of defendants' "good deeds and character"; mission statement was likely relevant to "the jury's consideration of a punitive damages award").

Plaintiffs' suggestion that "good company" evidence could be reserved to a future punitive damages phase also fails. Trial has not been bifurcated. All of Plaintiffs' claims will be decided at once by the same jury, including punitive damages. Unless Plaintiffs agree to waive their punitive damages claims, Defendants must be allowed to present such relevant evidence.

21. Defendants cannot postulate a "but-for" world in which the contamination was disclosed earlier and the contaminated API and VCDs would have remained available for purchase.

Plaintiffs generically argue that Defendants should not be allowed to suggest to the jury "what the 'but-for' world might have looked like" if the presence of NDMA had been "fully disclosed earlier than . . . in 2018." (Mot. at 33.) Because Plaintiffs do not point to any specific evidence that they are seeking to exclude, their motion is procedurally improper. Opinion at 2-3, *United States v. Janssen Prods.*,

L.P., No. 12-07758, ECF 330 (D.N.J. June 28, 2023) ("*Janssen* Op.") (Davidson Cert. Ex. 3) ("The movant bears the burden of demonstrating that the evidence is inadmissible on any relevant ground, and the court may deny a motion in limine when it lacks the necessary specificity with respect to the evidence to be excluded.").

To the extent Plaintiffs take issue with Dr. Stiroh's opinion that the at-issue VCDs had value notwithstanding the presence of nitrosamines, Plaintiffs' motion is meritless. As set forth in Defendants' response to Plaintiffs' motion to exclude Dr. Stiroh's opinions, evidence of the economic impact if the VCDs had not been on the market is highly relevant to Plaintiffs' theory of injury. Moreover, Plaintiff appear to misinterpret Defendants' evidence. Dr. Stiroh has never suggested that Defendants would have continued selling VCDs after learning about the nitrosamine impurities. Rather, her expert opinion is that the consumers had already taken the at-issue VCDs paid for by the TPPs and received the therapeutic benefits of these drugs once the impurities were discovered. Thus, Dr. Conti should have, at the very least, "allowed for a partial reduction in value" to account for these benefits. (ECF 2630-1, ¶ 8(i)(b).) At no point does Dr. Stiroh postulate a but-for world in which VCDs containing nitrosamines should have or would have remained on the market after the nitrosamines were discovered.

22. Defendants cannot reference double or treble damages, attorney fees, statutory penalties, pre- or post-judgment interest.

Defendants do not seek to reference double damages, treble damages,

attorneys' fees, statutory penalties or pre- or post-judgment. Accordingly, this motion is moot. Defendants do intend to probe the class representative's financial interest in this case, which is appropriate to "dispel any notion in the jury's mind that the [plaintiff] has no stake in this case and is thus free of bias." *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, No. 95-1231, 2007 WL 851868, at *1 (D.D.C. Mar. 14, 2007) (defendant is free to cross-examine relator about "fact that he stands to share in any recovery, and even what his proportional share is likely to be").

23. Defendants cannot argue they complied with SOPs, guidances, or regulations without specifically identifying same; and specifically-referenced SOPs must have been produced in discovery.

Defendants do not intend to argue that they complied with individual SOPs, guidances or regulations that are not specifically identified at trial or that were not produced in discovery. However, Defendants should be able to point to the absence of evidence of violations of their SOPs, guidances or regulations, given Plaintiffs' burden. In addition, Plaintiffs should be precluded from arguing that Defendants failed to comply with any SOPs, guidances, or regulations without specifying them, and Plaintiffs should be precluded from arguing generally that Defendants' SOPs and quality systems were inadequate without specific reference to admissible evidence supporting those statements.

24. Defendants cannot refer to their API or VCDs as "life saving" or similar descriptions.

Defendants should not be barred from describing VCDs as lifesaving and arguing that their therapeutic benefits outweigh nitrosamines' risks. ***First***, evidence of VCDs' therapeutic effects is relevant to the parties' claims and defenses. Fed. R. Evid. 401, 402. As discussed above, Plaintiffs' theory that the at-issue VCDs were economically worthless is a "central trial issue." (ECF 2261, 37-38 & n.27.) To decide this issue, the jury must consider the undisputed value of the therapeutic benefits provided by the at-issue VCDs. (Mot. at 35 ("That fact that the valsartan controlled blood pressure is not at issue.").) As explained above (*see supra*, Opp'n to MIL 21), Defendants' expert Dr. Stiroh will testify that Plaintiffs' worthlessness theory has no economic basis because the presence of nitrosamines cannot retroactively eliminate all economic value. (ECF 2630-1, ¶¶ 8(i), 17.) Defendants must be permitted to explain to the jury the positive value provided by the at-issue VCDs, including their potential to save lives.

Second, accurately describing VCDs and their effects does not raise Rule 403 concerns. Plaintiffs do not cite any authority indicating that it does, and courts presiding over similar cases regularly refuse to exclude references to the therapeutic benefits or lifesaving characteristics of a product. *See, e.g.*, *Keen*, 480 F. Supp. 3d at 652 (denying motion to exclude references to medical devices as lifesaving); *Coker v. C.R. Bard, Inc.*, No. 13-CV-515, 2023 WL 3857584, at *1 (N.D. Ga. Jan. 3, 2023) (denying motion in limine to description of product as "Life-Saving"). Descriptors

like "lifesaving" or "beneficial" cannot be misleading here because they are accurate. VCDs lower blood pressure, which, in turn, reduces the risk of premature death, heart failure, stroke, and chronic kidney failure—all of which could otherwise be fatal.[4] Evidence of VCDs' therapeutic benefits also ensures a fair trial. Plaintiffs intend to argue that the at-issue VCDs cause cancer. Precluding Defendants from describing the life-saving benefits of VCDs would unfairly prevent Defendants from telling the jury the other side of the story. *See Keen*, 480 F. Supp. 3d at 652 (evidence that a product is lifesaving "is not irrelevant and unduly prejudicial merely because it conflicts with one party's side of the story").

25. Defendants cannot assert or argue that the prescription of VCDs was standard of care.

Plaintiffs' motion to exclude references to VCDs as the standard of care should be denied. Once again, Plaintiffs cannot show that the evidence is irrelevant; they simply disagree with it. But that is no basis to exclude evidence, and in any event, Defendants have presented undisputed expert evidence that valsartan was a recommended treatment for hypertension.[5] Moreover, Defendants do not argue that

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[4] (*See* ECF 2298-3, 8-9; ECF 2572 at Ex. 74, 2 ("[W]e strongly believe the risks, such as stroke, of abruptly discontinuing these important medicines far outweighs the low risk associated with continuing the medications with these impurities.").)

[5] (*See* ECF 2298-3, 8-9 (citing 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the *(cont'd)*

only valsartan could be prescribed to treat hypertension, as Plaintiffs suggest. (*See, e.g.*, ECF 2298-3, 17 ("If the VCDs that were later recalled had been unavailable or could not be purchased during the period between 2012 and 2018, practitioners would have prescribed alternative antihypertensive drugs to patients who used these medications . . . ."); ECF 2630-1, ¶ 38 ("To assess economic make-whole damages, one must also analyze the but-for prices that TPPs would have paid for replacement medications . . . .").) Thus, Plaintiffs' motion is meritless.

26. ZHP Defendants cannot assert any evidence or argument inconsistent with their filed stipulations.

ZHP does not intend to present evidence at trial that contradicts what the stipulation referenced by Plaintiffs actually says. ZHP opposes Plaintiffs' motion, however, to the extent Plaintiffs seek to interpret the stipulation in a manner that would bar ZHP from presenting evidence or argument regarding issues that go beyond the specific facts included in the stipulation. For example, Plaintiffs suggest that the stipulation "demonstrates the complete lack of scientific analysis" by ZHP with respect to the "introduction of the DMF and TEA" to the manufacturing process for valsartan. But the stipulation merely addresses specific aspects of the risk

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American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Hypertension 2018;71:e13-e115 at e43-44 ("[T]he primary agents used in the treatment of hypertension include . . . ARBs [which comprise valsartan].")).)

assessment with respect to the valsartan manufacturing process change—i.e., the potential degradation of DMF—and provides an explanation of the change request form. These stipulated facts do not preclude ZHP from arguing, consistent with statements by the FDA, that neither ZHP nor regulators had reason to expect the degradation of DMF at the time of the process change, or from presenting evidence regarding the extensive scientific analysis ZHP conducted as part of approving the manufacturing change.

Moreover, for all the reasons explained in the TPP Trial Defendants' motion in limine regarding litigation conduct and discovery disputes (Defs.' MIL 3), the Court should preclude plaintiffs from offering any evidence or argument regarding the reasons for the stipulation beyond what is stated in the document, including any reference to plaintiffs' meritless request for discovery sanctions or any alleged discovery misconduct.

27. Defendants cannot argue that Teva's and Torrent's VCDs were not adulterated because the FDA did not issue Warning Letters to them.

Teva and Torrent should be allowed to argue that their VCDs were not adulterated due to the absence of FDA Warning Letters issued to them.

First, the absence of FDA Warning Letters to Teva and Torrent is probative of their defense that their VCDs were not adulterated. Fed. R. Evid. 401, 402. Each of Plaintiffs' claims is based in part on allegations that Torrent's and Teva's VCDs were "adulterated." (ECF 1708, ¶¶ 623-624, 628-630 (First Cause of Action), ¶ 641

(Second Cause of Action), ¶¶ 691-694 (Fifth Cause of Action), ¶¶ 727-728, 730-732, 737 (Seventh Cause of Action).) A drug is deemed to be "adulterated" only under specific circumstances outlined in the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). *See* 21 U.S.C. §§ 351(a)-(d). A violation of FDCA requirements and a finding of adulteration can only be made by the FDA, however, because "[t]he FDA—and the FDA alone—has the power and the discretion to enforce the FDCA." *Allergan, Inc. v. Athena Cosms., Inc.*, 738 F.3d 1350, 1359 (Fed. Cir. 2013).[6] Here, the FDA never completed even the preliminary step of issuing a non-determinative Warning Letter, much less making a formal finding of adulteration. The lack of an FDA Warning Letter or finding of adulteration is thus directly relevant to Teva's and Torrent's proofs that their products were not adulterated.

Second, contrary to Plaintiffs' accusations of sophistry, it is Plaintiffs who are misreading the Court's prior Rule 702 rulings and attempting to usurp the role of the FDA. Plaintiffs reason that because the Court found that one of Teva's defense experts could not opine that retrospective analyses are prohibited, that somehow

[6] *See also* 21 U.S.C. § 337(a) (vesting exclusive enforcement authority in the United States); *Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 787 (W.D. Tex. 2001) ("Claims of adulteration should be resolved by the FDA."); *Agee v. Alphatec Spine, Inc.*, No. 15-cv-750, 2017 WL 5706002, at *3-5 (S.D. Ohio Mar. 27, 2017) (granting motion to dismiss claims that were "clearly dependent upon the FDCA to a degree that the claims would not exist but for the statute"), *aff'd*, 711 F. App'x 791 (6th Cir. 2018) (per curiam).

constitutes an endorsement of any retrospective analysis Plaintiffs might offer. But as already discussed, the Court was clear that its ruling was meant only to exclude improper "legal opinion[s]," and likewise prohibited Plaintiffs' experts from offering their own legal opinions on adulteration. (*See supra*, Opp'n to MIL 1.) The Court certainly did not vest Plaintiffs with the FDA's statutory powers or abrogate the FDA's exclusive right to determine adulteration—whether prospectively or retrospectively. And it certainly does not mean that the absence of such a determination by the FDA is irrelevant.

Third, Torrent and Teva have never acknowledged that the issuance of a Warning Letter to ZHP is dispositive as to their VCDs. To the contrary, they previously argued that the mere issuance of a warning letter does not create a presumption of adulteration because "warning letters from the FDA do not mark the consummation of the agency's decision-making process." (ECF 2570-1, 9 n.6 (quoting *Rosas v. Hi-Tech Pharms.*, No. 20-00433, 2020 WL 5361878, at *3 (C.D. Cal. July 29, 2020)); *see also* ECF 2603, 2, 12-13.) And, again, Plaintiffs cite no authority in support of their argument that a finding of adulteration against an API manufacturer inherently applies to finished dose manufacturers. In any event, this is a merits issue for the jury, not an issue for a motion in limine.

28. Defendants cannot argue that they complied with cGMPs in the manufacture of the API and VCDs.

Plaintiffs again seek (improperly) to use a motion in limine to repeat

(meritless) summary judgment arguments. CGMPs are a central fact question, and Defendants have adduced ample evidence that they did comply with cGMPs, as set forth in their summary judgment opposition incorporated herein. (ECF 2603, 19.) As set forth in that response, the November 29, 2018 Warning Letter to ZHP is not an FDA determination at all, much less irrebuttable proof of cGMP violations, and was not directed to Teva or Torrent. Plaintiffs' disagreement is not a basis for precluding evidence or argument. *See SEC v. Revelation Cap. Mgmt., Ltd.*, 215 F. Supp. 3d 267, 278 (S.D.N.Y. 2016) ("[D]isagreement over the interpretation of the documents and testimony and is not grounds for exclusion."). Defendants would be severely prejudiced if they were essentially unable to defend their manufacturing practices for the VCDs at issue, and Plaintiffs offer no legitimate reason to prevent them from doing so.[7]

29. Defendants cannot argue that the contaminated API and VCDs were not adulterated

Plaintiffs' motion to prohibit Defendants from arguing that their VCDs were not adulterated once again rehashes their motion for summary judgment. This motion fails for the same reason as MILs 27 and 28. The Court has never ruled that

[7] Although Plaintiffs' motion seeks to preclude all Defendants from arguing that they complied with cGMPs, Plaintiffs do not even attempt to present a basis for prohibiting Torrent and Teva from submitting evidence on this point and thus doubly fails to carry their burden as to Torrent and Teva.

the FDA's warning letters affirmatively established for purposes of this litigation that Defendants' API and VCDs were adulterated under 21 U.S.C. §§ 351(a)(2)(B) or (b). Instead, the Court has consistently ruled time and again that whether Defendants' products were adulterated is a fact question for the jury to decide. Plaintiffs' effort to remove relevant issues from trial and to supplant the jury is improper and would result in error if granted for all the reasons already stated. (ECF 2584, 26:3-6 ("[P]lease don't make the mistake of disguising dispositive motions as in limine motions, because I'll just deny them out of hand.").)

30. Defendants cannot argue that the contamination was unavoidable or unforeseeable.

Plaintiffs seek to preclude Defendants from arguing that the purported contamination of their VCDs was "unavoidable" or "unforeseeable," repeating their litigation theory that Defendants have "refused to take responsibility for" their actions. (Mot. at 41.) However, Plaintiffs once again fundamentally misapprehend the purpose of a motion in limine, which is a "means of addressing the ***admissibility*** of evidence" rather than "arguing that the opposing party's legal arguments on the merits of the case are incorrect." *Laskowski*, 2011 WL 5040953, at *4 (emphasis added). While Plaintiffs insist that the FDA purportedly found that the presence of trace amounts of nitrosamines was in fact foreseeable in its Warning Letter (*see* Mot. at 41), Defendants vigorously disagree with that interpretation, particularly in light of other statements by the FDA that "neither regulators nor industry fully understood

how NDMA could form" during ZHP's manufacturing process. (*See* ECF 2572 at Ex. 1, 1; ECF 2572 at Ex. 64, 4.) It is up to the "jury, as finder of fact and weigher of credibility," to "assess all evidence which might bear" on this question. *See Gonzalez*, 155 F. App'x at 582 (citation omitted); *see also DeFrischia v. N.Y. Cent. R.R. Co.*, 307 F.2d 473, 476 (3d Cir. 1962) ("[K]nowledge of the likelihood of injury is imparted by information of like occurrences under similar circumstances, and is a fact to be considered by a jury . . . .") (citation omitted).

31. Defendants cannot argue that Teva's and Torrent's VCDs were not adulterated because the FDA never declared their VCDs did not meet USP standards or never de-listed the VCDs from the Orange Book.

This is yet another motion in limine seeking to advance Plaintiffs' summary judgment arguments regarding adulteration and should be denied for all the same reasons set forth in Defendants' response to MIL 27. Plaintiffs' motion falsely assumes that whether the at-issue VCDs met USP standards and were therapeutically equivalent to branded VCDs is "not up for debate." Rather, this issue was subject to extensive summary judgment briefing (*see* ECF 2603, 15-19, 25-29), which the Court has yet to address. To the extent the Court does not decide those issues in defendants' favor at summary judgment, Teva and Torrent should not be precluded from explaining to the jury that their products did comply with USP standards and were never de-listed from the Orange Book.

32. Teva and Torrent cannot argue that they were not responsible for the quality of the API incorporated into their finished dose VCDs.

This motion effectively asks the Court to force Teva and Torrent to accept strict liability for ZHP's API. The issue of responsibility for the quality of the API, as well as Teva's and Torrent's own finished dose products, is an ultimate issue for the jury to decide and not appropriately resolved via a motion in limine.

Plaintiffs mischaracterize the deposition testimony referenced in Plaintiffs' MIL 2 and conflate Teva's and Torrent's responsibility for meeting applicable standards with the ultimate issue of liability. (ECF 2009-29 at Ex. 216, 41:25-42:2 ("[T]o talk about it generally in terms of responsibility and liability is not something I dealt with in my report.").) To the extent Plaintiffs assert that Defendants have already "admitted responsibility," Plaintiffs may cross-examine Defendants' witnesses regarding their prior statements. Teva and Torrent should likewise be permitted to present evidence and testimony explaining how they met their responsibilities by complying with applicable ICH guidelines, cGMPs and compendial specifications, and the jury can decide. (ECF 2571, ¶¶ 99-101.)

Plaintiffs' reliance on *United States v. Vepuri*, No. 21-132, 2022 WL 541772, at *3-8 (E.D. Pa. Feb. 23, 2022), is misplaced. There, the defendants were charged with knowingly purchasing drugs the FDA had deemed "adulterated," lying to the FDA, failing to report manufacturing changes, and failing to correct the FDA's report based on their falsehoods. *Id.* at *3-8. Teva and Torrent never made false reports or changes to their processes without FDA approval, and at all relevant times

received acceptable cGMP inspections. (*See* ECF 2571, ¶¶ 18-21.)

33. Defendants cannot raise the notice issues raised on the dispositive motions at trial.

Because it is undisputed that MSP did not provide ***any*** pre-suit notice for its breach of express warranty claims, the Court should resolve this issue by granting summary judgment in Defendants' favor. If it does not, Defendants are entitled to offer evidence that Plaintiffs did not provide pre-suit notice, which is a required element of their breach of express warranty claims. (*See* ECF 2261, 44; ECF 2261-1, F-9, F-26 to F-27, F-32 to F-50; ECF 2261-2, G-45, G-48 to G-53.) Plaintiffs have previously argued that sufficiency of notice is a fact question for the jury. (*See* ECF 2606, 9.) *See also BK Trucking Co. v. PACCAR, Inc.*, No. 15-2282, 2016 WL 3566723, at *7 (D.N.J. June 30, 2016) (adequacy of notice is "generally a question of fact for the jury"). Moreover, many of the express warranty states' pattern jury instructions specifically include a notice element and/or definition. *See*, *e.g.*, Mont. Pattern Civ. Jury Instr. 14.12; Neb. Jury Instr. (NJI) 2d Civ. 11.45; 1 Nev. Pattern Jury Instr. Civ. 7.16; 1 N.H. Civ. Jury Instr. 23.11 (2022); RIJIC § 2010.1; MUJI 2d CV 1041; WCPJI Civ. § 13.06. Accordingly, Defendants may challenge the existence or sufficiency of pre-suit notice at trial.

34. Defendants cannot assert irrelevant, confusing, misleading, or unduly prejudicial background facts about MSP or its assignors.

Plaintiffs' motion seeking to exclude evidence related to MSP should be

denied because it is overbroad, premature and seeks to exclude relevant evidence.

First, motions in limine "that encompass broad classes of evidence, should generally be deferred until trial to allow for the resolution of questions of . . . relevancy[] and potential prejudice in proper context." *Martin v. Finley*, No. 15-CV-1620, 2019 WL 1473430, at *1 (M.D. Pa. Apr. 3, 2019) (citation omitted); *Elm Cooper, LLC v. Modular Steel Sys., Inc.*, No. 19-CV-01053, 2020 WL 905532, at *3-4 (M.D. Pa. Feb. 25, 2020) (similar). This is particularly true where, as here, the motion "fails to describe the supposedly objectionable evidence with sufficient specificity." *Apotex, Inc. v. Cephalon, Inc.*, No. 06-cv-2768 et al., 2017 WL 2362400, at *7 (E.D. Pa. May 31, 2017); *see also, e.g.*, *Dandy v. Ethicon, Inc.*, No. 20-431, 2023 WL 2714072, at *15 (D.N.J. Mar. 30, 2023) (similar).

Second, evidence related to MSP's background and business model will clearly be relevant and admissible at trial. The jury will need to understand MSP's structure and role as an assignee to understand why it is in this lawsuit. And understanding the challenges the company faces will almost certainly be relevant to gauging the motivations, credibility and reliability of company witnesses and evidence. This applies to the six topics listed by Plaintiffs.

Litigation Between Life Wallet And Cano Health. Plaintiffs first seek to preclude reference to a lawsuit filed against MSP Recovery, Inc. ("LifeWallet") by Cano Health, one of MSPRC's assignors and one of the parent's major investors.

(*See* Mot. at 46.) Plaintiffs claim the lawsuit is irrelevant because it does not specifically name the party in this case, but rather its "thrice-removed corporate parent." (*Id.*) Plaintiffs' insistence on strict adherence to corporate separateness is difficult to take seriously given that MSPRC itself does not even own the assignments on which it is trying to sue; each is owned by a subsidiary. (*See* ECF 2637-1, 25.) That is consistent with the longstanding practice of the MSP companies to "play fast and loose with" the corporate form. *MAO-MSO Recovery II, LLC v. Mercury Gen.*, No. 17-02525, 2021 WL 3615905, at *6 (C.D. Cal. Aug. 12, 2021) (citation omitted). In any event, there is no rule against reference to an entangled parent company at trial, since "parent companies often have an influence on subsidiaries." *ICTSI Or., Inc. v. Int'l Longshore & Warehouse Union*, No. 12-cv-1058, 2019 WL 1651038, at *14 (D. Or. Apr. 17, 2019) (denying in substantial part motion to exclude reference to parent company). That is clearly the case here, where the companies have aligned interests and work together for their mutual benefit, something the terms of one of the assignments at issue in this litigation makes clear. (*See* ECF 2009-5 at Ex. 41 (assigning tens of thousands of dollars in SummaCare claims from MSP Recovery, LLC ("MSPR LLC") to Series 16-11-509 LLC for nominal $10 consideration).)

Criminal And Civil Securities Fraud. Plaintiffs next seek to preclude reference to investigations into Life Wallet and MSPR LLC by the Securities and

Exchange Commission and United States Attorney's Office. However, "[e]vidence about the integrity, motivation, and conduct of [named] plaintiffs [in a class action] may have relevance so long as that evidence is tied to an issue in the case—including bias—and not merely a generalized attack on character."[8] *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, MDL No. 2785, 2022 WL 226130, at *7 (D. Kan. Jan. 26, 2022). Factors like bias and credibility are clearly relevant here since MSPRC representatives will be testifying at trial. Plaintiffs claim this evidence would present "the risk of undue prejudice." (Mot. at 47.) But without reference to any specific evidence, much less discussion of the prejudice it might carry, it has not come close to showing that such prejudice "***substantially*** outweigh[s]" this potentially significant probative value. Fed. R. Evid. 403 (emphasis added).

MSP's Business Model. MSP wants to hide its business model from the jury: a model it essentially concedes consists of aggregating claims and "rushing to file litigation" on them, *MAO-MSO Recovery II, LLC v. State Farm Mut. Auto. Ins. Co.*, 994 F.3d 869, 878 (7th Cir. 2021); *see MSP Recovery Claims, Series LLC v. N.Y. Cent. Mut. Fire Ins. Co.*, No. 19-CV-00211, 2019 WL 4222654, at *6 (N.D.N.Y.

[8] These bases for admission were not at issue in the two cases on which Plaintiffs rely, *Bhaya v. Westinghouse Elec. Corp.*, 922 F.2d 184 (3d Cir. 1990) and *In re Bankatlantic Bancorp, Inc. Secs. Litig.*, No. 07-61542, 2010 WL 11426137 (S.D. Fla. Aug. 18, 2010) (both cited in Mot. at 47).

Sept. 5, 2019) ("throw their allegations into as many federal courts as possible [to] see what sticks"). Defendants will not belabor the judiciary's uniform disapproval of this "abusive litigation," *State Farm*, 994 F.3d at 871. However, some discussion of the issue is relevant for several reasons. For starters, some courts have found motive for filing a suit, which clearly implicates MSP's business model, to be relevant to credibility. *See, e.g.*, *O'Brien v Middle East Forum*, No. 19-cv-06078, 2021 WL 5873006, at *1 (E.D. Pa. July 28, 2021); *Wood v. Winnebago Indus., Inc.*, No. 18-CV-1710, 2022 WL 2373672, at *2 (D. Nev. June 30, 2022) ("entitled to introduce evidence of [plaintiff's] motives, intent, interests, and objectives for filing, pursuing, and participating in this lawsuit"). In addition, MSPRC's "opportunistic [and] litigious" business model (Mot. at 48) is clearly relevant to the credibility of any MSP statements that the jury will need to evaluate. It is likewise relevant to the nature of MSPRC's assignments and particularly to the question of champerty—whether they took the assignments at issue solely "for the purpose of" suing on them, N.Y. Jud. Law § 489—which, as discussed below, may be a live issue. Once again, Plaintiffs have not articulated any specific prejudice that would flow from evidence of this type such that it should be precluded before trial.

LifeWallet's Financial Condition. Plaintiffs' perfunctory argument that LifeWallet's financial condition is "irrelevant and would only serve to confuse and mislead the jury" (Mot. at 49) fails for many of the same reasons as its other

arguments. The financial condition (both of MSPRC and its parent) is clearly relevant to motivations and bias, and therefore to a jury's evaluation of credibility. *See In re EpiPen*, 2022 WL 226130, at *7; *Holt v. Lewsader*, No. 18-CV-2169, 2021 WL 4094996, at *11 (C.D. Ill. Apr. 19, 2021) ("may argue that [p]laintiff has a financial debt relevant to [p]laintiff's motive for filing suit"). As mentioned above, the jury will need to evaluate the credibility of MSP and its employees, particularly as to damages but perhaps also as to other issues such as the validity of assignments. Financial bias is a classic basis for challenging credibility.

Issues Related To MSP's Assignors. Plaintiffs seek to exclude "irrelevant, confusing, and unduly prejudicial arguments . . . related to MSP's assignors." (Mot. at 50.) At that level of generality, Plaintiffs ask the Court to do little more than restate Federal Rules of Evidence 401 and 403. In reality, Plaintiffs want to hide the fact that the federal government suspended SummaCare from the Medicare program for failure to comply with requirements and regulations. SummaCare's violations stemmed in large part from its "ineffective monitoring and oversight of [its] Pharmacy Benefit Manager ('PBM'), which is responsible for SummaCare's coverage determinations." (Mot. Ex. 45, at 3.) Since the payments at issue in this litigation were made primarily to the PBM (which in turn paid for the VCDs in the first instance), this "ineffective monitoring" calls into question the reliability of SummaCare's payment data, and therefore of MSPRC's claimed damages, and is

relevant for that reason. It also calls into question any claim that SummaCare relied on any statements by Defendants in covering the medications at issue.[9]

MSP's Status As An Enrollee. Finally, Plaintiffs ask the Court to "exclude any argument or evidence that would highlight MSP's status as an assignee" rather than a health plan that paid for at-issue VCDs. (Mot. at 50.) Of course, it would be impossible to hold this trial while pretending that MSP is actually a Medicare Part D plan or other health insurer. Defendants assume that Plaintiffs seek only to limit references to its status as an assignee, but that status presents an unavoidable central issue. Defendants have a right to challenge the validity of the assignments on which Plaintiffs purport to sue, especially since MSPRC and its affiliates have regularly failed to establish a proper chain of assignments from a validly injured party. *See, e.g.*, *MSP Recovery Claims, Series LLC v. USAA Gen. Indem. Co.*, No. 18-21626, 2018 WL 5112998, at *9 (S.D. Fla. Oct. 19, 2018) ("It is [p]laintiff's burden to show a valid assignment exists.").

In addition, MSPRC's role as an assignee is relevant because any assignments it (or its subsidiaries) did receive may be void for champerty. Under New York law, which governs with respect to the Emblem claim, an assignment is void if taken

[9] In addition, to the extent Plaintiffs' counsel opens the door by extolling the assignors' corporate citizenship or role in the healthcare system, Defendants should be entitled to provide a full picture, which includes violations the federal government termed "a serious threat to the health and safety of enrollees." (Mot. Ex. 45, at 3.)

primarily for the purpose of filing a lawsuit. *See* N.Y. Jud. Law § 489; *Justinian Cap. SPC v. WestLB AG*, 65 N.E.3d 1253, 1256 (N.Y. 2016). Likewise, under Ohio law, which governs the SummaCare claim, an assignment of a contingent future interest is void, *see W. Broad Chiropractic v. Am. Fam. Ins.*, 912 N.E.2d 1093 (Ohio 2009), as is an assignment by which one "undertakes to further another's interest in a suit in exchange for a part of" recovery, *Hiles v. NovaStar Mortg., Inc.*, No. 12-cv-392, 2012 WL 4813775, at *4 (S.D. Ohio Oct. 10, 2012) (citation omitted). As MSPRC itself has argued, "champertous intent is a fact-sensitive inquiry." *MSP Recovery Claims, Series LLC v. Abbott Lab'ys*, No. 19-21607, 2021 WL 2177548, at *10 (D.N.J. May 28, 2021). The jury will need facts to evaluate it.

The validity of the assignments is a live issue in this trial. Plaintiffs have not moved for partial summary judgment on the issue. And they cannot do so now in the guise of a motion in limine.

35. Defendants cannot argue or suggest that TPP Trial Subclass Plaintiffs/Members will retain any benefit and not pass it along to their insureds.

Defendants do not intend to argue what Plaintiffs will, or will not, do with any damages they may be awarded unless Plaintiffs open the door by, for example, improperly suggesting that they will pass on any awarded damages to insureds through lower premiums. To the extent Plaintiffs do make that argument, Defendants should not be precluded from rebutting it.

36. Defendants cannot argue Medicare Part D Offsets (collateral source; reconciliation process).

Plaintiffs duplicate their misplaced collateral source arguments from their Motion to Exclude Opinions of Wayne Gibson. (*See* ECF 2631, 7-9.) Defendants incorporate by reference their response in opposition to that motion.

As before, Plaintiffs make no attempt to fulfill their duty to "apply the collateral source rule" under the applicable law of the 42 states at issue for the claims at issue. *In re Air Crash Disaster Near Chicago*, 803 F.2d 304, 308 (7th Cir. 1986). They ignore the fact that the collateral source rule categorically does ***not*** apply to breach of express warranty claims, which sound in contract. *See Asher v. Unarco Material Handling, Inc.*, 862 F. Supp. 2d 551, 554-55 (E.D. Ky. 2012) (collecting cases). They further ignore that the collateral source rule does ***not*** apply where the payments received "are not payments of compensation for the plaintiff's injury or loss," but "a completely independent act," *Rametta v. Stella*, 572 A.2d 978, 979-82 (Conn. 1990), as is the case with the CMS subsidy payments, which are contractual payments negotiated between CMS and TPPs to cover specific drug costs. And they ignore that state legislatures "throughout the United States" have partially or wholly abrogated the common law collateral source rule. *Reid v. Williams*, 964 P.2d 453, 457 n.7 (Alaska 1998). Finally, Plaintiffs' authorities are inapposite, because they involve, at most, applications of the collateral source rule to different claims under

different circumstances.[10] For all of these reasons, the motion should be denied.

37. Defendants cannot suggest that there should be set offs for unquantified, speculative subsidies and reimbursements.

Plaintiffs reference various arguments from their Motion to Exclude Opinions of Wayne Gibson (ECF 2631, 4-10), seeking to exclude so-called "unquantified, speculative subsidies and reimbursements." Defendants again incorporate their opposition to that motion by reference. As explained in more detail in that opposition: (1) the CMS subsidies amount to costs the TPP class members ***did not incur***, and it is for the jury to decide how they should be factored into damages; (2) Mr. Gibson has quantified and substantiated each of the subsidies; (3) Defendants' rebuttal damages experts are not required to put forth an alternative damages calculation; and (4) the entire thrust of Mr. Gibson's testimony is that Plaintiffs' misplaced focus on the "point of sale" results in a wholly inaccurate calculation. Plaintiffs cannot assume away his valid criticisms.

Special Master Vanaskie recognized the relevance of subsidies and

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[10] *See In re HIV Antitrust Litig.*, No. 19-cv-02573, 2023 WL 3603732, at *2 (N.D. Cal. May 23, 2023) (applying unspecified states' collateral source rules to state antitrust claims and acknowledging that the rule requires a "tortfeasor" and payments enabling the "victim" to "later escape[] some of the consequences of the harm"); *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 18-md-2836, 2023 WL 3064462, at *5 (E.D. Va. Apr. 18, 2023) (not discussing collateral source rule and only finding that evidence of "pass-on overcharges" was too attenuated). Plaintiffs' remaining cases all involve purely compensatory medical benefits or unemployment insurance payments in personal injury of wrongful termination cases.

reimbursements last year, albeit in the discovery context. As the Special Master explained, "[t]he extent to which [TPP] payments were offset by . . . reimbursements"—in the context of CMS reimbursements—"appears clearly relevant to the determination of actual damages sustained by the alleged contamination of the VCDs." *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 19-2875 (RBK), 2023 WL 8071595, at *2 (D.N.J. Jan. 24, 2023) (citing *In re Namenda Indirect Purchaser Antitrust Litig.*, No. 15-cv-6549, 2022 WL 3362429, at *11 (S.D.N.Y. Aug. 15, 2022) ("Any benefits, including discounts or subsidies, that flowed to a plaintiff must be used to reduce the amount of damages suffered by that plaintiff. Therefore, as a matter of law, to the extent [c]lass [m]embers receive any form of payment that covers all or part of its . . . prescription costs, those payments must be deducted from damages.")). Although that decision was made in the discovery context, the principle underlying it (i.e., that calculating actual damages requires inquiry into subsidies and reimbursements that lowered the prices paid for an at-issue VCD) supports the relevance of this evidence at trial.

38. Defendants cannot reference the dollar amounts for which they sold the API and VCDs, and the amounts of the reimbursements requested and/or agreed to with regard to downstream customers.

Defendants do not oppose the portion of Plaintiffs' motion seeking to exclude "[t]he amounts for which the API and VCDs were sold by Defendants into the supply chain." (Mot. at 56.) However, Defendants do oppose the exclusion of evidence of

"any reimbursements [that] were offered, made available, or paid by Defendants to any downstream customer." (*Id.*) This latter category of evidence is relevant to Plaintiffs' actual damages in this case and is also highly probative of whether Defendants' conduct rises to the level of malice and reprehensibility necessary to sustain a punitive damages award.

First, reimbursements given to downstream customers, including TPPs, are plainly relevant to the extent that such reimbursements affected the amount of money a TPP paid for at-issue VCDs. Under the subclass states' fraud and warranty laws, Plaintiffs will need to prove either "[o]ut-of-pocket damages," which "represents the difference between the price paid and the actual value received," or benefit-of-the-bargain damages, which represents "the difference between the price paid and the value of the property had the representations been true." *Finderne Mgmt. Co. v. Barrett*, 955 A.2d 940, 957 (N.J. Super. Ct. App. Div. 2008) (citation omitted). (*See also* ECF 2562-1, 34-37.) Thus, whether a TPP received any sort of reimbursement which altered the "price paid" is highly relevant to establishing the appropriate amount of actual damages. (*See also supra*, Opp'n to MIL 37 (citing Special Master Vanaskie's ruling recognizing the relevance of subsidies).)

Second, whether Defendants offered to reimburse downstream customers, including non-TPP customers, for their purchases of allegedly contaminated VCDs is relevant to the calculation of any punitive damages. While the applicable states

vary considerably in the standard for punitive liability, many require that "the harm was the result of intentional malice, trickery, or deceit, or mere accident." *Heckadon v. CFS Enters., Inc.*, 400 S.W.3d 372, 382 (Mo. Ct. App. 2013) (citation omitted); *see also, e.g.*, *Gargano v. Heyman*, 525 A.2d 1343, 1347 (Conn. 1987) ("[T]he flavor of the basic requirement to justify an award of punitive damages is described in terms of wanton and malicious injury, evil motive and violence."). Further, determining the appropriateness of a punitive damages award requires an inquiry into the "[r]eprehensibility" of a defendant's conduct, which "should be discounted if defendants act promptly and comprehensively to ameliorate any harm." *In re Exxon Valdez*, 270 F.3d 1215, 1242 (9th Cir. 2001).

Evidence that Defendants offered reimbursements is relevant under these standards because it directly rebuts Plaintiffs' allegation that they acted maliciously and reprehensibly. Indeed, if this evidence were excluded, Plaintiffs would be allowed to paint a distorted picture of Defendants' alleged conduct, shielding jurors from any steps Defendants took to "ameliorate any harm" they allegedly caused while Plaintiffs promote their dubious theory that Defendants placed "profit" over "safety." (ECF 2569-1, 1.) *See, e.g.*, *In re Exxon*, 270 F.3d at 1242; *see also Fab-Tech, Inc. v. E.I. DuPont De Nemours & Co.*, 311 F. App'x 443, 448 n.3 (2d Cir. 2009) (defendant's actions in "ceas[ing] its objectionable acts and attempt[ing] to conform its behavior" to breached contract "fail to demonstrate the requisite 'degree

of malice' necessary to support punitive damages") (citation omitted). In short, admission of reimbursements would provide the jury with the full picture of Defendants' alleged conduct—the probative value of which would substantially outweigh any risk of jury confusion or delay. *See Watson v. County of Santa Clara*, No. C-06-04029, 2012 WL 6025787, at *3 (N.D. Cal. Dec. 4, 2012) ("A district court may, in its discretion, allow a defendant to introduce evidence of remedial conduct undertaken in response to his wrongful act as a factor mitigating punitive damages.").

39. Defendants cannot disparage the insurance industry.

The Court should reject Plaintiffs' "request that the [c]ourt prohibit [Defendants] from making disparaging comments about . . . insurance companies in general" because it "is too broad a request for the [c]ourt to grant in limine." *Anderson v. Shelter Mut. Ins. Co.*, No. 13CV00087, 2015 WL 11090407, at *2 (E.D. Ark. Mar. 12, 2015); *see also Janssen* Op. at 2-3 ("The movant bears the burden of demonstrating that the evidence is inadmissible on any relevant ground, and the court may deny a motion in limine when it lacks the necessary specificity with respect to the evidence to be excluded."). To the extent this issue arises at trial, Plaintiffs will be able to raise objections and the Court will be able to consider the propriety of those objections in the context of specific statements, evidence, or argument instead.

In any event, Defendants should be allowed to inform the jury who the Plaintiffs are: a class of insurance companies seeking to recover alleged economic losses as well as an entity that purchased the claims of two of those insurance companies, not individual consumers who allegedly contracted cancer. The Plaintiffs' identities are relevant to many of the issues in this case. For example, Defendants need to be able to explain to the jury that the issue of TPP-reliance is distinct from consumer-reliance or prescriber-reliance, which requires discussion of the fact that the class is comprised of insurance companies. Damages issues similarly require educating the jury on who Plaintiffs are and their role in paying for VCDs, which necessarily involves discussion of the nature of their businesses.

40. The Court should not permit Defendants to discuss how a verdict would economically affect either Defendants or society. This sort of conjecture is non-probative, prejudicial, and should be excluded.

Defendants do not intend to present evidence of the parties' size and wealth, except to defend themselves against Plaintiffs' punitive damages claims—a purpose found admissible by the Supreme Court and other federal courts. *See, e.g.*, *City of Newport v. Fact Concerts, Inc.*, 453 U.S. 247, 270 (1981) ("[E]vidence of a [defendant]'s wealth is traditionally admissible as a measure of the amount of punitive damages that should be awarded."); *Rafael Hurtado v. Balerno Int'l Ltd.*, No. 17-62200, 2019 WL 917404, at *2 (S.D. Fla. Feb. 25, 2019) ("And, where there is a claim for punitive damages, 'a defendant's financial condition becomes relevant

because the wealth of the defendant is a factor for consideration in determining the reasonableness of a punitive award.'") (citation omitted). Plaintiffs do not dispute that the parties' relative wealth is relevant to punitive damages. (Mot. at 57 ("This motion does not address arguments that may be made in connection with a punitive damages phase.").) As explained above (*see supra*, Opp'n to MIL 20), Plaintiffs' suggestion that evidence of the parties' size and financial position could be reserved to a future punitive damages phase fails because trial has not been bifurcated. Unless Plaintiffs agree to waive their punitive damages claims, Defendants must be allowed to present evidence relevant to that issue.

41. Defendants cannot argue TPP Trial Subclass Plaintiffs/Members are "sophisticated users" (see affirmative defense).

The "sophisticated user" defense is an ultimate issue for the jury to decide and not appropriately resolved via a motion in limine. (ECF 2584, 26:3-6 ("[P]lease don't make the mistake of disguising dispositive motions as in limine motions, because I'll just deny them out of hand.").) "Motions in limine are a means of addressing the admissibility of evidence, and it is an improper technique for arguing that the opposing party's legal arguments on the merits of the case are incorrect." *Laskowski*, 2011 WL 5040953, at *4.

42. Defense counsel should be barred from suggesting that they are one in the same as Defendants by using the terms "we," "us," and/or "our" when referring to Defendants. Such statements are irrelevant, inaccurate, and prejudicial.

Plaintiffs seek to bar defense counsel from using first-person pronouns (e.g., "we," "us," and/or "our") when referring to Defendants, arguing that such statements would be irrelevant, inaccurate and prejudicial. (Mot. at 58.) In so arguing, Plaintiffs are attempting to import the general proscription against improperly vouching for parties or witnesses in criminal cases into the civil arena. The two, however, are not analogous. Whereas "vouching" by government prosecutors may influence jurors in a criminal trial, "in a civil case in which the government is not a party, the concern that jurors will be swayed by one attorney's comments on the evidence or a witness's credibility does not exist." *Schmitz v. City of Wilsonville*, No. 96-1306, 1999 WL 778586, at *5 (D. Or. Sept. 17, 1999). In any event, even if this concept were applicable in the civil context, there would be instances in a multi-week trial where counsel's use of "we" or "us" would clearly not constitute improper vouching—for example saying "we" (Defendants through counsel) established certain facts. Accordingly, a blanket in limine prohibition against the use of common pronouns would not be proper; rather, any issue regarding the use of pronouns should be addressed at trial. *See In re Aqueous Film-Forming Foams Prods. Liab. Litig.*, MDL No. 2873, 2023 WL 3686120, at *1 (D.S.C. May 26, 2023) ("The [c]ourt denies the motion and will address issues related to improper vouching and/or pronoun use if

and when they arise at trial.").[11]

43. Defendants cannot criticize plaintiff attorneys, plaintiffs for bringing lawsuits, or reference attorney advertising.

Plaintiffs seek to bar Defendants from "attack[ing]" "plaintiffs and plaintiff attorneys." (Mot. at 59.) Defendants have no intention of attacking either Plaintiffs or their attorneys, rendering this portion of Plaintiffs' motion moot.

Defendants do oppose Plaintiffs' motion to the extent it seeks to preclude Defendants from raising the issue of lawsuits or attorney advertising. While Plaintiffs assert in a conclusory manner that such evidence is "irrelevant" (Mot. at 59), references to attorney advertising and "lawyer-driven litigation" "relat[e] to [p]laintiffs' decision to file the case at bar" and are therefore "relevant to [p]laintiffs' credibility." *See Herrera v. Eli Lilly & Co.*, No. 13-02702, 2015 WL 12911753, at *4 (C.D. Cal. Aug. 3, 2015) (denying similar motion in limine to the one here). Indeed, the fact that a plaintiff may have seen attorney advertising prior to commencing suit speaks directly to the nature of his or her alleged injuries and the veracity of the plaintiff's claims regarding those injuries. *See, e.g.*, *Sutphin v. Ethicon, Inc.*, No. 14-01379, 2020 WL 5079170, at *2 (S.D. W. Va. Aug. 27, 2020)

[11] Plaintiffs' sole case expressly "recognizes there may be inadvertent references when counsel for either side are referring to something they have done in the course of the litigation on behalf of their clients," but that "counsel should avoid making a personal connection with their clients in front of the jury." *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, No. 19-2885, 2021 WL 918214, at *6 (N.D. Fla. Mar. 10, 2021) (cited in Mot. at 58).

(denying motion to exclude evidence regarding attorney advertising because "whether a plaintiff saw an attorney advertisement prior to filing suit [is] 'probative of . . . credibility regarding . . . injuries'") (citation omitted); *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327, 2014 WL 505234, at *3 (S.D. W. Va. Feb. 5, 2014) (denying motion in limine to exclude evidence that plaintiff "was prompted by a television commercial to file suit" because the evidence was "probative of her credibility regarding her injuries").

These principles apply directly to MSP, which has chosen to purchase assignments of claims for the purpose of suing on behalf of other purportedly injured TPP subclass members. *See In re EpiPen*, 2022 WL 226130, at *7 (denying similar motion to exclude use of the phrase, "'lawyer-driven' lawsuit" in class action trial because "[e]vidence about the integrity, motivation, and conduct of *plaintiffs* may have relevance so long as that evidence is tied to an issue in the case—including bias"). Given the enormous stakes of this trial, it is especially critical that Defendants have a full and fair opportunity to test MSP's credibility, particularly with regard to the fundamental issue of injury.

Plaintiffs offer no reason why this evidence is irrelevant or unfairly prejudicial other than to claim that the phrase "'lawyer-driven litigation' . . . is very similar to, and will evoke similar prejudices as the phrases 'litigation crisis,' and 'lawsuit abuse,' which Defendants have already agreed not to mention." (Mot. at 59.) Most

of the cases Plaintiffs cite are inapposite precisely because they only precluded the use of the specific terms or phrases that Defendants have already agreed not to use. *See In re Bard IVC Filters*, 2018 WL 934795, at *2 (excluding references to "litigation crisis" and "tort reform") (citation omitted); *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2005 WL 3164251, at *1 (E.D. La. Nov. 18, 2005) (excluding references to "litigation crisis," "lawsuit crisis," and "lawsuit abuse"); *In re Actos (Pioglitazone) Prods. Liab. Litig.*, MDL No. 11-2299, 2013 WL 5603823, at *2 (W.D. La. Oct. 10, 2013) (same); *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2006 WL 8472994, at *1 (E.D. La. Nov. 22, 2006) (same). Only one case cited by Plaintiffs, *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, MDL No. 2592, 2017 WL 11718344, at *2 (E.D. La. Apr. 18, 2017), excluded references to "[l]awyer-[d]riven [l]itigation" and that case did so without explanation, and it should not be followed.

Plaintiffs are also wrong that evidence regarding MSP's business practice of filing lawsuits is barred by Rule 404(b). (*See* Mot. at 60-61.) Defendants do not offer this evidence to show that MSP has a propensity for litigation. Rather, as set forth above, the purpose of this evidence is to probe MSP's credibility, motivation for filing suit, and its claim of injury—which even Plaintiffs' own authority recognizes is permissible. *See Otto v. Com. St. Cap.*, No. 12-2472, 2013 WL 2357623, at *2-3 (E.D. Pa. May 29, 2013) (denying motion to exclude evidence of plaintiff's prior lawsuits because such evidence "supports defendants' argument that [plaintiff's]

claim for damages in the instant case is not credible"); *see also Barbee v. Se. Pa. Transp. Auth.*, 323 F. App'x 159, 162 (3d Cir. 2009) (affirming district court decision to admit evidence concerning plaintiff's involvement in 24 prior civil suits for impeachment purposes); *Strategic Partners, Inc. v. Figs, Inc.*, No. 19-02286, 2022 WL 18399950, at *5 (C.D. Cal. Sept. 26, 2022) (denying motion to exclude evidence regarding plaintiff's prior litigation where defendant argued that evidence was relevant to, among other things, credibility for plaintiff's damages claim). The other cases cited by Plaintiffs are not to the contrary. In *Blancha v. Raymark Industries*, 972 F.2d 507, 516 (3d Cir. 1992), the Third Circuit did not address the admissibility of the plaintiff's prior lawsuits, and in the other two cases, the defendants failed to articulate the relevancy of the prior lawsuits. *See Ostroff v. Sec. Sav. Bank*, No. 90-6920, 1992 U.S. Dist. LEXIS 12322, at *4 (E.D. Pa. Aug. 18, 1992); *Covell v. Bell Sports, Inc.*, No. 09-2470, 2010 WL 11561087, at *2 (E.D. Pa. July 13, 2020). Accordingly, Plaintiffs' motion should be denied.

44. The manner in which Plaintiff learned about this litigation or their attorneys, and when or why they retained their attorneys to represent them, is irrelevant and unrelated to Plaintiff's claims and subject to attorney-client privilege.

Plaintiffs seek to exclude the manner in which Plaintiffs learned about this litigation or their attorneys, and when or why they retained their attorneys to represent them. (Mot. at 61-62.) This motion should be denied for the same reasons as the prior motion: the evidence is relevant to whether Plaintiffs have suffered any

injury as a result of Defendants' alleged conduct and also bears on Plaintiffs' and MSP's credibility and their motivation to file this lawsuit. Plaintiffs have offered no explanation for why this evidence would be unfairly prejudicial, other than speculating that the evidence would focus the trial on counsel's behavior and "inappropriately appeal[] to any bias jurors may have." (Mot. at 62.) That is not sufficient to show undue prejudice. Plaintiffs are also wrong that this evidence is subject to the attorney-client privilege. Defendants do not seek to elicit testimony regarding Plaintiffs' discussions with counsel or counsel's strategy, but rather the facts that led to Plaintiffs' filing of this lawsuit.

45. Defendants cannot inject arguments regarding the consumers' damages or suggest consumers benefitted.

Defendants do not intend to discuss the details of the consumers' claims, except to the extent required to explain to the jury the scope of the upcoming trial (e.g., that the Plaintiffs are TPPs asserting economic loss claims, not individual consumers who allegedly suffered either financial or personal injuries).

However, to the extent Plaintiffs seek to preclude Defendants from presenting evidence that the at-issue VCDs provided therapeutic benefits to consumers and thus had value as a matter of economics, Defendants oppose this motion. As explained above (*supra*, Opp'n to MILs 21 and 24), evidence of therapeutic benefits is relevant to the parties' damages arguments, does not raise Rule 403 concerns, and should not be precluded.

46. Defendants cannot seek sympathy for big corporations targeted in litigation, or assert that they employ people in New Jersey.

Plaintiffs' motion to preclude any statements attempting to mitigate jurors' potential bias against large corporations like Defendants should be denied because the jury has the right to a full understanding of the case, including some detail about the parties involved. Allowing Defendants to respond to potential negative statements or inferences about large corporations would be consistent with the purpose of Rule 403, because it would modify the risk of unfair prejudice. *See Rawcar Grp., LLC v. Grace Med., Inc.*, No. 13-cv-1105, 2014 WL 12199979, at *2 (S.D. Cal. Oct. 21, 2014) (agreeing in part with defendants' argument that "the jury should be able to hear basic facts about the parties"). Defendants also should be permitted to reference where they employ people to combat the heightened concern of bias against large nonresident corporations. The U.S. Supreme Court has recognized the risk that juries may be "influenced by prejudice against large corporations" and that this risk "is of special concern when the defendant is a nonresident." *TXO Prod. Corp. v. All. Res. Corp.*, 509 U.S. 443, 464 (1993) (plurality opinion).

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motions in limine.

Dated: February 26, 2024

Respectfully submitted,

By: */s/ Jessica Davidson*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 26, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
Jessica Davidson